## ORDER OF THE MISSOURI BOARD OF PHARMACY ISSUING TELEFLEX MEDICAL INCORPORATED A DRUG DISTRIBUTOR LICENSE SUBJECT TO PROBATION

Comes now the Missouri Board of Pharmacy ("Board") and issues its ORDER granting a PROBATED drug distributor license, license number 2008007907, to Teleflex Medical Incorporated ("Teleflex Medical") pursuant to the provisions of Section 620.149, RSMo. As set forth in Section 620.149, RSMo, Teleflex may submit a written request for a hearing to the Administrative Hearing Commission seeking review of the Board's decision to issue a probated license to Teleflex Medical. Such written request must be submitted to the Administrative Hearing Commission within thirty (30) days of issuance of this Order. The written request should be addressed to the Administrative Hearing Commission, P.O. Box 1557, Truman Building Room 640, Jefferson City, MO 65102-1557. If no written request for review is received by the Administrative Hearing Commission within the thirty (30) day period, the right to seek review of the Board's decision shall be waived.

The disciplinary period shall become effective immediately upon issuance of Teleflex Medical's permanent license as a drug distributor. Should Teleflex Medical file a written request for review of this Order, the terms and conditions of this Order shall remain in force and effect unless and/or until such time as the Administrative Hearing Commission issues an order contrary to this Order.

## FINDINGS OF FACT

- 1. The Missouri Board of Pharmacy (hereinafter "Board") is an agency of the State of Missouri created and established pursuant to Section 338.110, RSMo, for the purpose of executing and enforcing provisions of Chapter 338, RSMo.
- 2. Teleflex Medical Incorporated filed an application for a drug distributor license with the Board on January 30, 2008. This initial application filed by Teleflex Medical had erroneous information on the application submitted to the Board by it, which was corrected only after it was brought to its attention by staff of the Board.
- 3. Teleflex Medical shipped legend drugs into Missouri without first obtaining a drug distributor license from the Board in violation of Chapter 338, RSMo.

- 4. Teleflex Medical agreed that it shipped legend drugs into Missouri without first obtaining a drug distributor license from the Board in violation of Chapter 338, RSMo.
- 5. Based on information received by the Board, pursuant to Section 338.055, RSMo, the Board concluded Teleflex Medical engaged in conduct which would be grounds for denying Teleflex Medical a license, or if currently licensed by the Board, disciplinary action by the Board against its drug distributor license.
- 6. Teleflex Medical received warning letters from the Federal Drug Administration on July 20, 2006, for federal drug law violations at one of its facilities in North Carolina, and a warning letter for numerous federal drug law violations on October 10, 2007, for one of its subsidiaries at two facilities owned by the subsidiary in Maine and North Carolina.
- 7. Pursuant to the provisions of Section 620.149, RSMo, the Board hereby issues drug distributor license number 2008007907 to Teleflex Medical Incorporated in lieu of denial of Teleflex Medical's request for a Missouri drug distributor license. License number 2008007907 is issued subject to the terms and conditions set forth herein below.

## **CONCLUSIONS OF LAW**

- 8. Teleflex Medical's conduct as alleged above is cause for the Board to deny Teleflex Medical a drug distributor license pursuant to Section 338.055.1 and .2, RSMo, which states in pertinent parts:
  - 1. The board may refuse to issue any certificate of registration or authority, permit or license required pursuant to this chapter for one or any combination of causes stated in subsection 2 of this section. The board shall notify the applicant in writing of the reasons for the refusal and shall advise the applicant of his or her right to file a complaint with the administrative hearing commission as provided by chapter 621, RSMo.
  - 2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:

(6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;

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- 9. Section 620.149, RSMo, provides in pertinent part:
  - 1. Whenever a board within the division of professional registration, including the division itself when so empowered, may refuse to issue a license for reasons which also serve as a basis for filing a complaint with the administrative hearing commission seeking disciplinary action against a holder of a license, the board, as an alternative to refusing to issue a license, may, at its discretion, issue to an applicant a license subject to probation.
- 10. The Board hereby issues this ORDER in lieu of denial of Teleflex Medical Incorporated's request for a Missouri drug distributor license pursuant to Section 620.149, RSMo.

## **ORDER**

Based on the foregoing and in lieu of denying Teleflex Medical Incorporated a drug distributor license, the Board issues Teleflex Medical Incorporated a license subject to PROBATION for five (5) years (hereinafter "disciplinary period"). The terms of discipline shall be:

- a. Teleflex Medical shall pay all required fees for licensing to the Board and shall renew its drug distributor license prior to October 31 of each licensing year.
- b. Teleflex Medical shall comply with all provisions of Chapter 338, Chapter 195, and all applicable federal and state drug laws, rules and regulations and with all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.
- c. If, after disciplinary sanctions have been imposed, the Teleflex Medical fails to keep its drug distributor license current, the period of unlicensed status shall not be deemed or taken as any part of the time of discipline so imposed.
- d. Teleflex Medical shall report to the Board, on a preprinted form supplied by the Board office, once every six (6) months, beginning six (6) months after this Order is entered, stating truthfully whether or not it has complied with all terms and conditions of this disciplinary order.
- e. Teleflex Medical shall make a representative of the drug distributor available for personal interviews to be conducted by a member of the Board or the Board of Pharmacy staff. Said meetings will be at the Board's discretion and may occur

periodically during the disciplinary period. Teleflex Medical will be notified and given sufficient time to arrange these meetings.

- f. Teleflex Medical's failure to comply with any condition of discipline set forth herein constitutes a violation of this disciplinary Order.
- g. The parties to this Order understand that the Board of Pharmacy will maintain this Order as an open record of the Board as provided in Chapters 338, 610, 620, RSMo.

Upon the expiration of the disciplinary period, Teleflex Medical's license as a drug distributor shall be fully restored if all other requirements of law have been satisfied; provided, however, that in the event the Board determines that Teleflex Medical has violated any term or condition of this Order, the Board may, in its discretion, after an evidentiary hearing, vacate and set aside the discipline imposed herein and may suspend, revoke, or otherwise lawfully discipline Teleflex Medical's drug distributor license.

No order shall be entered by the Board pursuant to the preceding paragraph of this Order without notice and an opportunity for a hearing before the Board in accordance with provisions of Chapter 536, RSMo.

If the Board determines that Teleflex Medical has violated a term or condition of this Order, which violation would be actionable in a proceeding before the Administrative Hearing Commission or the Circuit Court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this Order in its determination of appropriate legal actions concerning that violation.

SO ORDERED this 28th day of May, 2008

MIŠSOURI BOARD OF PHARMACY

DEBRA C. RINGGENBERG, R.Ph EXECUTIVE DIRECTOR